K113380

510(k) Summary

Date Prepared:	November 15, 2011
Applicant:	Medtronic Neuromodulation 7000 Central Ave., N.E. Minneapolis, MN 55432 Establishment Registration Number: 2182207
Contact:	Thomas Reichel Regulatory Affairs Specialist Phone: 763-526-9693 Fax: 763-367-1694 (fax) Email: tom.j.reichel@medtronic.com
Alternate Contact:	Patrick Johnson Senior Director Regulatory Affairs Phone: 763-526-6735 Fax: 763-367-1694 (fax) Email: patrick.l.johnson@medtronic.com
Trade Name:	Prostiva RF Therapy Model 8929 Hand Piece Prostiva RF Therapy Model 8930 RF Generator Prostiva RF Therapy Model 8934 Return Electrode Prostiva RF Therapy Model 6101 Tubing System Prostiva RF Therapy Model 8099 Telescope Prostiva RF Therapy Model 8099TU15 Telescope
Classification Name:	21 CFR 876.4300 & 21 CFR 878.4400
Regulatory Name:	Endoscopic electrosurgical unit and accessories
Regulatory Classification:	Class II
Product Code:	KNS and GEI
Name of Predicate Device:	Prostiva RF Therapy Model 8929 Hand Piece (K101139) TUNA Therapy Model 8930 RF Generator (K052413) TUNA Therapy Model 8934 Return Electrode (K052413) TUNA Therapy Model 6101 Tubing System (K002583) TUNA Therapy Model 8099 Telescope (K002583)

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Device Description

Prostiva RF Therapy is a minimally invasive treatment for patients with lower urinary tract symptoms due to benign prostatic hyperplasia (BPH). Prostiva® RF Therapy System uses precisely focused radio frequency (RF) energy to ablate prostate tissue.

Indications for Use

The Prostiva RF Therapy System is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20 and 50 cm^3.

Performance Standards

No applicable mandatory performance standards or special controls exist for this device.

Substantial Equivalence

The historical changes in this submission did not involve changes to control mechanism, operating principles, energy type, indications, or sterilization process. None required clinical evidence to evaluate impact to safety and effectiveness. The changes were considered to be routine changes to maintain or improve device performance based on internal or external feedback and the information generated as part of design verification and validation activities or technical assessments confirmed these change did not adversely affect the device's safety or effectiveness.

For the proposed change to the manufacturing process of a potentially patient contacting material, an evaluation of supplier testing information confirms that the proposed change does not impact the safety or effectiveness of the device.

The currently marketed products are substantially equivalent to the previously submitted and cleared predicate products.

Summary of Testing

The device design and labeling changes discussed in this document have been verified and/or validated through proper Design Verification/Validation and/or Design Assurance Testing where deemed necessary and applicable.

Conclusion

The modifications to the Prostiva RF Therapy System described in this submission have not altered the fundamental scientific principle or indication of the devices. The current devices are substantially equivalent to the previously submitted and cleared predicate Prostiva RF Therapy and TUNA Therapy devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 15, 2012

Medtronic, Inc.
Neuromodulation
% Mr. Thomas Reichel
Senior Regulatory Affairs Specialist
7000 Central Ave., N.E.
MINNEAPOLIS MN 55432

Re: K113380
Trade/Device Name: Prostiva RF Therapy Model 8929 Hand Piece
Prostiva RF Therapy Model 8930 RF Generator
Prostiva RF Therapy Model 8934 Return Electrode
Prostiva RF Therapy Model 6101 Tubing System
Prostiva RF Therapy Model 8099 Telescope
Prostiva RF Therapy Model 8099TU15 Telescope
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KNS, GEI
Dated: November 8, 2012
Received: November 13, 2012

Dear Mr. Reichel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement Form

510(k) Number (if known): K113380

Device Name: Prostiva RF Therapy Model 8929 Hand Piece
Prostiva RF Therapy Model 8930 RF Generator
Prostiva RF Therapy Model 8934 Return Electrode
Prostiva RF Therapy Model 6101 Tubing System
Prostiva RF Therapy Model 8099 Telescope
Prostiva RF Therapy Model 8099TU15 Telescope

Indications for Use:

The Prostiva RF Therapy System is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20 and 50 cm^3.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X___ OR Over-The-Counter Use _____
Per 21 CFR 801.109

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K113380